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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,793	11/26/2003	Miguel Corona Villegas	2099.0070001/JAG/LBB	6600

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/721,793	CORONA VILLEGAS ET AL.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 26 November 2003.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, and 31, drawn to an isolated nucleic acid identified by SEQ ID NO's selected from the group listed, classified in class 536, subclass 23.1.

II. Claims 2, 5, and 9, drawn to an isolated polypeptide identified by SEQ ID NO's selected from the group listed, classified in class 530, subclass 300.

III. Claims 3, and 32, drawn to an isolated nucleic acid identified by SEQ ID NO's selected from the group listed, classified in class 536, subclass 23.1.

IV. Claims 4, 6, and 10, drawn to an isolated polypeptide identified by SEQ ID NO's selected from the group listed, classified in class 530, subclass 300.

V. Claims 7, 21-24, 40, and 41, drawn to an immunogenic or antigenic composition comprising at least on of the polypeptides of claim 2, wherein the polypeptide in the composition is bound to a polymer substrate, and a diagnostic device comprising the composition of claim 40, classified in class 530, subclass 402.

VI. Claims 8, 25-28, 43, and 44, drawn to an immunogenic or antigenic composition comprising at least on of the polypeptides of claim 4, wherein the polypeptide in the composition is bound to a polymer substrate, and a diagnostic device comprising the composition of claim 43, classified in class 530, subclass 402.

VII. Claims 11, 12, 33 in part, 36 in part, and 38, drawn to a method of preventing or treating envenomation from scorpion stings comprising administering to a

mammal an antigenic composition comprising at least one polypeptide of claim 2, classified in class 424, subclass 185.1.

VIII. Claims 13, 14, 33 in part, 36 in part, and 39, drawn to a method of preventing or treating envenomation from scorpion stings comprising administering to a mammal an antigenic composition comprising at least one polypeptide of claim 4, classified in class 424, subclass 185.1.

IX. Claims 15, 16, 33 in part, 34 in part, and 36 in part, drawn to a method of producing and recovering antibodies against a scorpion venom comprising injecting an antigenic composition comprising at least one polypeptide of claim 2, classified in class 530, subclass 403.

X. Claims 17, 18, 33 in part, 34 in part, and 36 in part, drawn to a method of producing and recovering antibodies against a scorpion venom comprising injecting an antigenic composition comprising at least one polypeptide of claim 4, classified in class 530, subclass 403.

XI. Claims 19, 35 in part, and 37 in part, drawn to a composition comprising a neutralizing antibody directed to the binding fragment of the polypeptide claim 2, wherein the polypeptide is from the genus *Centruroides*, classified in class 530, subclass 387.9.

XII. Claims 20, 35 in part, and 37 in part, drawn to a composition comprising a neutralizing antibody directed to the binding fragment of the polypeptide claim 4, wherein the polypeptide is from the genus *Centruroides*, classified in class 530, subclass 387.9.

XIII. Claim 29, drawn to a method of treating envenomation from scorpion stings comprising administering to a mammal, neutralizing antibodies directed to at least one polypeptide of claim 2 or a fusion protein thereof, classified in class 424, subclass 139.1.

XIV. Claim 30, drawn to a method of treating envenomation from scorpion stings comprising administering to a mammal, neutralizing antibodies directed to at least one polypeptide of claim 4 or a fusion protein thereof, classified in class 424, subclass 139.1.

XV. Claims 42, and 46 in part, drawn to a diagnostic method to determine the species of scorpion, drawn to the diagnostic device of claim 41, classified in class 424, subclass 9.1.

XVI. Claims 45, and 46 in part, drawn to a diagnostic method to determine the species of scorpion, drawn to the diagnostic device of claim 43, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-VI, XI, and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different chemical structures with different functions.

3. Inventions V and VII, IX, XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in materially different processes of use, such as treating envenomation as disclosed in Invention VII, or recovering antibodies as disclosed in Invention IX.

4. Inventions VI and VIII, X, XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in materially different processes of use, such as treating envenomation as disclosed in Invention VIII, or recovering antibodies as disclosed in Invention X.

5. Inventions XI and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of treating envenomation from a scorpion sting can be practiced with another materially different product as disclosed in Invention VII.

6. Inventions XII and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the process of treating envenomation from a scorpion sting can be practiced with another materially different product as disclosed in Invention VIII.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. The search of Inventions is not coextensive and would therefore be burdensome.

8. Claims 1-4 disclose a plurality of patentably distinct species comprising various isolated nucleic acids or isolated polypeptides identified with SEQ ID NO's. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Further, claims directed to the method of use of an isolated nucleic acid or polypeptide would require the selection of a single disclosed species to conduct a search.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 7, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER